

4-5 December 2024

09:00-17:00 / 09:00-17:00

MINUTES - Agreed on 19 December 2024

Location: Web-Conference

Attendees:

- Panel Members:

Ana Allende, Avelino Alvarez-Ordóñez, Valeria Bortolaia, Sara Bover-Cid, Alessandra De Cesare, Wietske Dohmen, Laurent Guillier, Lieve Herman, Liesbeth Jacxsens, Maarten Nauta, Lapo Mughini-Gras, Jakob Ottoson, Luisa Peixe, Fernando Perez-Rodriguez, Panagiotis Skandamis, Elisabetta Suffredini

- Hearing Experts¹:

Romolo Nonno (item 8.5)

- European Commission and/or Member States representatives:

Kris De Smet, Gunilla Eklund (EC DG SANTE)

- EFSA:

Simone Baldassa, Sandra Correia, Maria Teresa Da Silva Felicio, Nadya Doyle, Nuria Ferrer, Raquel Garcia-Fierro, Beatriz Guerra, Michaela Hempen, Kamela Kryemadhi, Ernesto Liebana, Winy Messens, Angel Ortiz-Peláez, Hanne Rabbas, Valentina Rizzi, Mirko Rossi, Eleonora Sarno, Ancuta Cezara Simon, Pietro Stella, Frank Verdonck (BIOHAW Unit)

Ricardo Carvalho Rodrigues (COM Unit), Cristina Croera (FIP Unit), Laura Martino (MESE Unit)

- Others:

Observers (see Annex 1)

1. Welcome and apologies for absence

Apologies were received from Sara Bover-Cid for absence during part of the meeting on 4 December.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management,³ EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



4. Brief introduction of Panel members to Observers

The BIOHAZ Panel members briefly introduced themselves to the observers.

5. Presentation of EFSA Guidelines for Observers

EFSA BIOHAZ Panel Coordinator introduced the EFSA Guidelines for observers, including the rules for attending the meeting, and explained when in the agenda specific slots for answering questions from the observers have been placed.

6. Agreement of the minutes of the 173rd Panel Plenary meeting held on 23-24 October 2024

The minutes of the 173rd Panel plenary meeting were agreed by written procedure on 7th November 2024.

7. Scientific outputs submitted for adoption/endorsement

7.1 Scientific opinion on microbiological hazards associated with the use of water in postharvest handling and processing operations of fresh and frozen fruits, vegetables and herbs – parts 2-5 ([EFSA-Q-2023-00073](#), [EFSA-Q-2023-00074](#), [EFSA-Q-2023-00075](#) and [EFSA-Q-2023-00076](#)), including associated outsourcing activities (OC/EFSA/BIOCONTAM/2021/02)

The last WG meeting took place on 30th October 2024. The three 'sector-specific draft opinions for Fresh-whole, Fresh-cut and Frozen FVHs (Parts 3 to 5)' as well as the 'model draft opinion' were tabled for possible adoption. The most critical points raised by the Panel were addressed and all 4 opinions were unanimously adopted by the BIOHAZ Panel. The last changes implemented in the Annex on the 'multivariable logistic regression model' used across all sector-specific opinions were presented to inform the Panel. The Panel was presented with an overview of the multiple outputs associated to this mandate, i.e. opinions, reports and links with access to relevant files. The work on the development of the R Shiny app is still ongoing with some delay. In case it won't be possible to finalise it by the internal publication deadline for the opinions, the synchronised publication of all output of the mandate will be slightly delayed until mid-February.

7.2 Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA. 21: Suitability of taxonomic units notified to EFSA until September 2024 ([EFSA-Q-2021-00773](#))

The last meeting was held on 22nd October 2024. 54 notifications were received between April and September 2024 (inclusive): 33 as feed additives, 17 as food enzymes, food additives and flavourings, 4 as novel foods and none as PPPs. From these 54, 21 were not evaluated because they belong to taxonomic units excluded from the QPS evaluation (12 filamentous fungi, 1 *Enterococcus faecium*, 8 *E. coli*), and 29 belong to taxonomic units that already have a QPS status. Two of the remaining 4 notifications were already assessed before: *Ensifer adhaerens* (assessed within PS 19), which was not included now, and *Enterococcus lactis* (assessed within PS 15), which was re-assessed for a QPS status. The other 2, corresponding to 2 TUs, were also evaluated for a possible QPS status: *Serratia plymuthica* and *Lactocaseibacillus huelsenbergensis*. An extra microorganism was added in November per an urgent request - *Bacillus nakamurai* and evaluated for a possible QPS status. The ELS was finalised and its summaries were included in the text. The assessment of a possible QPS status for *B. thuringiensis* was finalised by the WG. The statement was adopted by the Panel.



8. Scientific outputs submitted for discussion

8.1 Scientific opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA ([EFSA-Q-2023-00054](#))

The last meeting of the WG dealing with QPS-related items was held on 22nd October 2024. The different sections of the draft opinion are being prepared and discussed by the QPS WG. The chapter on “QPS, new genetic techniques and synthetic microbiology” was presented to the Panel. The deadline for adoption of this opinion is 31st December 2025.

8.2 Guidance on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin ([EFSA-Q-2024-00020](#))

The comments received by the BIOHAZ Panel were addressed by the WG at their last WG meeting on 26th November 2024. The WG vice-Chair presented the revised draft opinion to the BIOHAZ Panel and the sections under the remit of the BIOHAZ panel were approved for public consultation. Subsequently, the draft was approved for public consultation by the EFSA Panel on Food Contact Materials, Enzymes and Processing aids. EFSA will launch the public consultation on the draft guidance on 18th December 2024 for 7 weeks⁴.

8.3 Scientific opinion(s) on the current status of the occurrence and spread of carbapenemase-producing Enterobacterales in the food chain in the EU/EFTA ([EFSA-Q-2024-00149](#))

The WG Coordinator and EFSA staff updated the Panel on the developments since the last Plenary. The last WG meeting before the Plenary was held on 11th November 2024, and the next meeting would be on 10th December 2024. Targeted EU-surveys to collect information from the MSs/EFTA countries on CPEs detection methods in use and existing control measures/contingency plans were sent. The surveys on on-going studies and positive findings will follow. The Monopole Framework Partnership Agreement with EU and National Reference Laboratories on antimicrobial resistance for the production of data related to testing protocols, for the performance of epidemiological investigations, for in depth genetic analyses of relevant resistant isolates (2024-2027), and for genomic comparison of isolates from different sources was just signed. The Part 1 scientific opinion currently under development focuses on the occurrence of CPEs in the food chain, transmission dynamics, detection methods, and existing control measures and contingency plans in EU/EFTA countries. It was presented for first reading and will be presented for adoption by the Panel by March 2025. The duration of the activities of the whole mandate is up to the end of 2027.

8.4 Scientific opinion on the equivalence of an alternative heat treatment process of feathers and down ([EFSA-Q-2024-00169](#))

Last WG meeting was held on 18th November 2024. The datasets (different products/temperature/times/aw) extracted from the extensive literature search were validated and analysed. No data were found for *E. faecalis* on dry heat. Limited data were found for the relevant viruses. For *S. Senftenberg* some data were found but were very discrepant. The Panel went through the text and focused on the draft replies to the two assessment questions. The possible ways to express the assessment conclusion (level of reduction) was thoroughly discussed and agreed. The deadline for adoption of this opinion is 31th January 2025.

⁴ <https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0ITk000003F74H/pc1253>



8.5 Scientific opinion on the presence of biological and chemical hazards in ash from Category 1 material after incineration, co-incineration, and combustion ([EFSA-Q-2024-00278](#))

The WG Chair presented the protocol for possible approval. The chair informed that, following the feedback of the Panel in the previous plenary with the request to have a meeting with the European Commission (EC) to explain the approach, EFSA called a meeting with the EC, EFSA staff and the chair of the WG. It took place on Thursday 21st November. After discussion and following the assessment questions (AQ) of the protocol presented to the Panel, a proposal of AQ and possible way to address the question that will allow to decide on ToR2, was sent after the meeting. In reply, the EC indicated that a yes/no answer is required and that the possible authorisation of Category 1 ash in organic fertilisers and soil improvers will require a revision of Regulation (EC) No 1069/2009 (a co-decision process) for which a high level of certainty is needed. The feedback was discussed in a WG meeting and substantial modifications were made to the protocol that was presented to the Panel at this plenary. The main reservation to the new protocol was the lack of structured uncertainty analysis. The WG chair explained that the sources of uncertainty will be described but the main assessment question is binary and will only be answered positively if there is a certainty greater than 99%. Minor modifications were made as a result of the comments by Panel members. Finally, the protocol was approved. The deadline for adoption of the opinion is 30 April 2025. The first draft of the opinion will be submitted for first reading in the next plenary in January 2025.

8.6 Scientific opinion on the microbiological safety of ungulates meat intended to be frozen ([EFSA-Q-2024-00663](#))

The Panel coordinator informed the Panel about the decision, taken in consultation with the BIOHAZ Panel Chair, that the mandate needs to be carried out by a new Working Group. After informing the Panel and in consultation with the BIOHAZ Panel Chair, Laurent Guillier was nominated Chair of the Working Group. The deadline for delivery of the scientific opinion is 31 October 2025. The Panel was also informed that discussions with the European Commission are ongoing with regard to a possible additional mandate on the same topic, specifically related to the stage of defrosting.

8.7 Application for alternative processing method for animal by-products: alkaline hydrolysis under atmospheric pressure ([EFSA-Q-2024-00286](#))

This agenda item was discussed under a Closed Session of the meeting. The WG Chair presented the draft opinion for thorough reading. He went through the comments provided by the Panel members, some of them already addressed before the plenary. The WG Chair read the amended conclusions, abstract and summary that were well received by the BIOHAZ Panel. In the next plenary, the draft opinion will be submitted for possible adoption. The non-confidential version of the dossier still needs to be subject for public consultation once the confidential claim assessment is finished. The deadline for adoption of the opinion is 20th February 2025.

8.8 Application for fluidized catalytic cracking co-processing for the production of renewable fuels ([EFSA-Q-2024-00539](#))

This agenda item was discussed under a Closed Session of the meeting. The WG Chair presented the draft opinion for the first time and for first reading. He went through the comments provided by the Panel members, some of them already addressed before the plenary. There were no major issues and the Panel agreed with the provisional conclusion of the opinion. The second WG meeting will take place on 9th January 2025 and a draft of the opinion will be submitted for thorough reading to the next plenary in January 2025.



8.9 Update of the scientific opinion 'Evaluation of the safety and efficacy of ListexTM P100 for reduction of pathogens on different ready-to-eat (RTE) food products' ([EFSA-Q-2024-00551](#))

This agenda item was discussed under a Closed Session of the meeting. The WG vice-Chair informed the Panel that the applicant has responded to the first request for information on 4th November 2024. A second request for information was sent to the applicant on 25th November 2024. Hence, the dossier has not yet been considered valid.

9. New mandates

No new mandates were received since the previous Plenary meeting.

10. Feedback from the Scientific Committee, other Scientific Panels, EFSA and the European Commission

10.1 Scientific Committee

The Panel Chair briefly reported to the BIOHAZ Panel the main topics discussed within the 122nd Plenary meeting of the Scientific Committee (SC), taking place on 20-21st November 2024⁵.

10.2 European Commission

The Panel coordinator updated the Panel on the possible future attendance by EC DG SANTE to the BIOHAZ Plenary meeting of March 2025. He also reported about recent ongoing discussions with the EC on a possible new mandate related to both animal health and public health aspects of highly pathogenic avian influenza.

10.3 Rapid Outbreak Assessments and related activities

EFSA staff from the BIOHAW Unit presented the latest published report on the assessment of a prolonged multi-country outbreak of *Salmonella* Strathcona ST2559 linked to consumption of tomatoes in the EU/EEA and the UK. The event background was followed by a description of the food investigation and the joint EFSA-ECDC assessment⁶.

11. Other topics for information and/or discussion

11.1 Implementation of the guidance on uncertainty analysis in scientific assessments

Relevant issues related to uncertainty analysis in specific mandates were tackled during the respective discussions in previous agenda items. No additional discussion took place. The Panel agreed to include this agenda item in future plenaries only when specific horizontal discussions on the implementation of the uncertainty guidance are needed.

⁵ <https://www.efsa.europa.eu/en/events/122nd-plenary-meeting-scientific-committee-open-observers>

⁶ <https://www.efsa.europa.eu/en/supporting/pub/en-9107>



11.2 Topics of scientific concern in the area of biological hazards

The Panel coordinator briefly reported to the Panel the discussions held during the last meeting of the EFSA Stakeholder Discussion Group on Emerging Risks (StaDG-ER), held on 28-29 November 2024⁷, about *Helicobacter pullorum*.

12. Answers to questions from Observers

The Panel answered the questions posed by observers through the registration form to the Open plenary before the meeting:

- **Question:** If there are AMR genes identified for the QPS listed bacteria proved to be intrinsic, is phenotypic MIC test still required?
Answer provided at the meeting: The data requirement for testing the AMR genes of bacterial strains are provided in the sectoral EFSA guidance documents. The data requirements for testing the AMR statement on the QPS qualification 'absence acquired AMR gene' will be stipulated in the 'Guidance on the characterisation and risk assessment of microorganisms used in the food chain' which is under development by EFSA and is currently under public consultation⁸ (open for comments until 7 February 2025).
- **Question:** For the MIC test, only ATCC strains can be used as QC strains? Or any well-characterized and documented strains with clear and trust MIC values can be employed as QC strains?
Answer provided at the meeting: For the MIC test no specific quality control strains are requested. As provided for in the FEEDAP EFSA guidance 'Guidance on the characterisation of microorganisms used as feed additives or as production organisms' (2018), the susceptibility test should be performed according to internationally recognised standards and should include the proper control strains.
- **Question:** EFSA guidelines specify that the antimicrobial production test should assess the inhibitory activity of culture supernatants against reference strains known to be susceptible to a range of antibiotics. EFSA listed some ATCC strain, would it be acceptable to use our own well-characterized strains, known to be susceptible to a range of antibiotics, for this test?
Answer provided at the meeting: The data requirements for testing the antimicrobial production of microorganisms are provided in the EFSA guidances, the FEEDAP EFSA guidance 'Guidance on the characterisation of microorganisms used as feed additives or as production organisms' (2018) and the 'Scientific guidance for the submission of dossiers on food enzymes' (2021). In these guidances, test against the reference strains according to the JECFA (FAO/WHO, 2006, Volume4) or Eucast (EUCAST 2015) are recommended. Other reference strains may be used provided that their choice is justified and their susceptibility to antibiotics is proven. These data requirements will be updated in the 'EFSA guidance on the characterisation and risk assessment of microorganisms used in the food chain' which as mentioned above is under development by EFSA and currently under public consultation.

No additional questions from observers were raised during the meeting.

13. AOB

No other points were raised for discussion under AOB.

⁷ <https://www.efsa.europa.eu/en/events/32nd-meeting-efsa-stakeholder-discussion-group-emerging-risks-stadg-er>

⁸ <https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0ITk0000035F1V/pc1221>



Annex 1 – List of Observers

23 Observers registered, 13 Observers attended the meeting.

Observer	Organisation
Andersson Maria	Anderssons Konsult och Förvaltning AB
Benkőová Brigita	Slovak Medical University
Damianos Alexandros	Aristotle University of Thessaloniki
Falcioni Ornella	Malta's Ministry for Agriculture, Fisheries and Animal Rights (MAFA)
Fasseas Michael	Greece's Ministry of Rural Development and Food
Ganbarzade Aygun	Azerbaijan Food Safety Institute
Geiser Stefanie	EAS Strategies
Heijkoop Jenny	Riskplaza BV
Lukanova Nadejda	Bulgaria's Risk assessment Centre on Food Chain
Morvan Ingrid	COMmittee Linking Entrepreneurship-Agriculture-Development (COLEAD)
Quaedvlieg Nicolette	The Fresh Produce Center
Tsitsos Anestis	Aristotle University of Thessaloniki
Zhu Hua	BaseClear